Baxter Healthcare Corporation 847.948.5311
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Dan Jernigan

Baxter

URGENT PRODUCT INFORMATION

September 6, 2002

RE: Meridian Hemodialysis Instrument and Medisystems Blood Tubing Interface (Medisystems Code D3-9694/9793 or K3-9694/9793)

Dear Hemodialysis Administrator:

Baxter Healthcare Corporation is participating in an investigation into reports of serious and unexpected patient reactions that have recently occurred in two U.S. dialysis centers. Preliminary reports suggest that there may have been five patient deaths and two patient injuries. The cause(s) of these events is as of yet undetermined. We are exploring the possibility that hemodialysis treatments may have employed common dialysis machines and bloodline setups.

The two reporting centers may have been using the following:
Blood Tubing – Medisystems Corporation, Code D3-9694/9793 or K3-9694/9793, Baxter code 5M9694
Hemodialysis Machine – Meridian

During the early course of our investigation, we have determined that this code of Medisystems blood tubing has the potential to kink when used with the Meridian machine. While we have no information that correlates this potential to the unexpected patient events, in the interest of patient safety:

Immediately discontinue the use of this Medisystems Blood Tubing (Medisystems Code D3-9694/9793 or K3-9694/9793) in conjunction with the Meridian machine.

Alternatives are Medisystems blood tubing with the following Baxter product code numbers: 5M9689 (Medisystems code K3-9689/9793), 5M9680M (Medisystems code D3-9680M9793), 5M9681M (Medisystems code D3-9681M9793).

Our Postmarket Surveillance Group at 1-888-736-2543, option 3, is available to assist with any urgent questions. The Food and Drug Administration has been notified of this communication.

Sincerely,

Michael S. Parkes

Michael S. Parkes
Vice-President, Quality Operations
Renal Division

cc: Hemodialysis Unit Administrator